

## **REMARKS**

### **Status of Claims and Amendment**

Upon entry of this amendment, which is respectfully requested, claims 1, 5 and 6 will be amended. Claims 4 and 9 have been canceled. Claims 12-16 are withdrawn from consideration as being directed to a non-elected invention. Claim 11 is allowed. Claims 1, 3, 5, 6, 8 and 10 are rejected. Claims 2 and 7 are objected to. Claims 1-3, 5-8 and 10-16 are all the claims pending in this application.

Claims 1 and 6 have been amended to replace the article “a” with the recitation of “the”.

Claim 5 has been amended to correct the claim dependency.

No new matter is added.

### **Claim of Priority**

Applicants thank the Examiner for acknowledging Applicants’ claim of priority to JP 2004-049123, as well as receipt of a certified copy thereof.

### **Withdrawn Rejection**

Applicants thank the Examiner for withdrawal of the rejection to claim 11 under 35 U.S.C. § 112, first paragraph.

### **Response to Objections**

#### **1. Objection to the Specification**

At page 3 of the Office Action, the specification is objected to for identifying “CYP93E1” as being SEQ ID NO: 8. The Office Action asserts that based on a nucleic acid

alignment between CYP93E1 and SEQ ID NO: 8, the nucleotide sequences of CYP93E1 and SEQ ID NO: 8 are distinct. Specifically, according to the Office Action's alignment, SEQ ID NO: 8 has a G at position 121, whereas CYP93E1 has an A at the corresponding position. The Office Action questions whether position 121 of SEQ ID NO: 8 should be A instead of G.

Applicants respectfully note that the specification clearly discloses that a cytochrome P-450 gene CYP93E1 (GenBank Accession Number AF135485, SEQ ID NO:10) only resembles the polynucleotide having SEQ ID NO:8. Furthermore, the specification discloses that "the polynucleotide represented by SEQ ID NO:8 and the polynucleotide represented by SEQ ID NO:10 are different from each other in terms of 3 positions of the 121st position, the 171st position and the 1081st position (hereinafter, the sequence represented by SEQ ID NO:8 is also called cytochrome P-450 gene CYP93E1 in some cases)." (See specification, page 4, lines 19-26 and page 5, line 1-5).

Withdrawal of the grounds of objection is respectfully requested.

## **2. Claim Objection**

At page 3 of the Office Action, claim 5 is objected to for the recitation of "claim 43" as there is no claim 43 present in the claim listing. The Office Action asserts that in the interest of advancing prosecution, claim 5 has been interpreted as being dependent upon claim 3, not claim 43.

Applicants respectfully submit that claim 5 was amended to depend on claim 3, but the knockout did not show clearly on the number 4. Accordingly, claim 5 has been amended to recite "claim 3" instead of "claim 43."

Withdrawal of the grounds of objection to claim 5 is respectfully requested.

## **Response to Rejections Under 35 U.S.C. § 112**

### **1. Written Description**

At page 4 of the Office Action, the rejection of claims 6, 8, and 10 is maintained under 35 U.S.C. § 112, first paragraph, for allegedly lacking written description.

The Office Action asserts that Applicants' argument that the genus of polynucleotides is adequately described in view of the claim 6 amendment to limit the members of the genus to "encoding for a polypeptide of SEQ ID NO: 9" is not found persuasive for the following reasons.

The Office Action asserts that in view of the broad interpretation of the article "a" in the phrase "a polynucleotide encoding a polypeptide of SEQ ID NO:9", this phrase only needs to encode at least two contiguous amino acids of SEQ ID NO: 9 and can encode any additional amino acid sequence at its 5'- and/or 3'-end(s). Thus, the Office Action alleges that the members of the genus only need to share a structural feature that encodes as few as two contiguous amino acids of SEQ ID NO: 9.

The Office Action also states that the description of the genus of  $\beta$ -amyrin synthase genes in claim 6 is no longer an issue.

In response, and solely to advance prosecution of the present application, claim 6 has been amended to replace "a" with "the".

Withdrawal of the rejection under § 112, first paragraph, is respectfully requested.

### **2. Enablement**

At page 5 of the Office Action, the rejection of claims 6, 8, and 10 is maintained under 35 U.S.C. § 112, first paragraph, as lacking enablement.

Applicants' argument in the Amendment filed on July 31, 2008 was not found persuasive because it is the Office Action's position that the specification is enabling only for an expression vector comprising a polynucleotide encoding the polypeptide of SEQ ID NO: 9 and a  $\beta$ -amylin synthase gene.

The Office Action appears to use the same reasons as discussed above under the written description rejection.

As discussed above, and solely to advance prosecution of the present application, claim 6 has been amended to replace "a" with "the".

Withdrawal of the rejection under § 112, first paragraph, is respectfully requested.

#### **Response to Rejection Under 35 U.S.C. § 102 (b)**

At page 8 of the Office Action, claim 1 is rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Steele *et al.* (Arch. Biochem. Biophys. 367:146-150, 1999) as evidenced by Shibuya *et al.* (FEBS J. 273:948-959, 2006)

Applicants' argument in the Amendment filed on July 31, 2008 that Steele *et al.* fail to teach an expression vector encoding "a polypeptide of SEQ ID NO: 9" was not found persuasive. The Office Action alleges that the language of claim 1 reciting a polynucleotide encoding for "a" rather than "the" polypeptide of SEQ ID NO: 9 includes any protein that has at least two consecutive amino acids in common with SEQ ID NO: 9 and that has activity to hydroxylate the 24-position of an oleanane type triterpene.

The Office Action asserts that Steele *et al.* teach a baculovirus expression vector with a nucleic acid comprising a CYP93E1 gene which encodes contiguous amino acids 42-513 of SEQ ID NO: 9. Further, the Office Action asserts that Shibuya *et al.* show that the polypeptide

encoded by the CYP93E1 gene of Steele *et al.* encodes a polypeptide that hydroxylates position 24 of  $\beta$ -amylin.

In response, and solely to advance prosecution of the present application, claim 1 has been amended to replace “a polypeptide” with “the polypeptide.”

Withdrawal of the rejection under U.S.C. § 102(b) is respectfully requested.

**Response to Rejection Under 35 U.S.C. § 103 (a)**

1. At page 10 of the Office Action, claim 3 is newly rejected and the rejection of claim 5 is maintained under 35 U.S.C. § 103 (a) as allegedly being unpatentable over Steele *et al.* (Supra) in view of Schopfer *et al.* (FEES Lett. 432:182-186, 1998).

Applicants’ argument in the Amendment filed on July 31, 2008 that the combination of references fails to teach an expression vector encoding “a” polypeptide of SEQ ID NO: 9 was not found persuasive since “a” polypeptide of SEQ ID NO: 9 is not limited to only the polypeptide of SEQ ID NO: 9.

In response, and solely to advance prosecution of the present application claim 1 has been amended to recite “the” polypeptide instead of “a” polypeptide.

Withdrawal of the rejection under § 103 (a) is respectfully requested

2. At page 11 of the Office Action, claims 6, 8, and 10 are newly rejected under 35 U.S.C. 103 (a) as allegedly being unpatentable over Morita *et al.* (Eur. J. Biochem. 267:3453-3460, 2000) in view of GenBank Accession Number AAA77063 and as evidenced by Invitrogen pYES2 vector map ([tools.invitrogen.com/content/sfs/vectors/pyes2\\_map.pdf](http://tools.invitrogen.com/content/sfs/vectors/pyes2_map.pdf)).

The Office Action uses the same rationale that the broad interpretation of the phrase “a” polypeptide of SEQ ID NO:9, could mean any contiguous amino acid sequence of SEQ ID NO: 9 of as few as two amino acids.

In response, and solely to advance prosecution of the present application claim 6 has been amended to recite “the” polypeptide instead of “a” polypeptide.

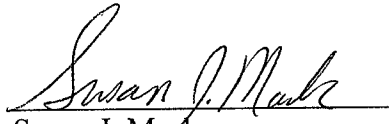
Withdrawal of the rejection under § 103(a) is respectfully requested.

**Conclusion**

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,

  
Susan J. Maek  
Registration No. 30,951

SUGHRUE MION, PLLC  
Telephone: (202) 293-7060  
Facsimile: (202) 293-7860

WASHINGTON DC SUGHRUE/265550

**65565**

CUSTOMER NUMBER

Date: February 12, 2009